REMARKS

Applicants thank the Examiner for the personal interview granted on July 8, 2003. As discussed during the interview, Applicants have amended claims 1 and 14 to clarify that the growth enhancing amount comprises DHA in an amount of at least about 10 mg/100 kcal and ARA in an amount of at least about 30 mg/100 kcal. These limitations are supported in the specification at page 6, lines 7 – 23. Applicants' proposed growth enhancing "amount" limitation was preliminarily viewed as favorable by the Examiner during the interview and it is respectfully submitted that the presently submitted claims are patentable over the cited prior art.

Claims 1 and 14 have been amended and new claims 21 and 22 have been added, without prejudice to Applicants' right to reassert the original claims in a divisional case which Applicants have filed simultaneously with the present amendment. The present Amendment is being made simply as a means to accelerate prosecution of the presently submitted claims separate from the original claims, while preserving the right to continue pursuing the previously submitted claims in the simultaneously-filed divisional case.

I. Rejection of claims 1-8 and 14-20 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,374,657 to Kyle

In the Office Action, the Examiner rejected claims 1-8 and 14-20 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,374,657 to Kyle (Kyle) further evidenced by Crozier, G.L., *et al.*, (Crozier) (Monatschrift Fur Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98). Specifically, the Examiner had stated that claims 1-8 and 14-20 read on the breast feeding of premature infants and that the claims were further

anticipated by Kyle, which teaches an infant formula comprising DHA and ARA in amounts comparable to that found in human breast milk.

In light of the present amendments to claims 1 and 14 requiring growth enhancing amounts of DHA of at least about 10 mg/100 kcal and ARA of at least about 30 mg/100 kcal, the fatty acid content of the presently claimed invention is not the same as that of either breast milk or Kyle. Kyle sets forth the amounts of individual fatty acids found in breast milk at Tables 2 - 6, col. 13 – 16 and then discloses a formula that attempts to mimic breast milk. Those amounts, in comparison to the claimed amounts of DHA and ARA in the present application, are set forth in the following table:

Fatty Acid	Applicants' Claimed Amounts	Breast Milk (as taught by Kyle)	Kyle Formula[1]
ARA	at least about 30 mg/100 kcal	26 mg/100 kcal	26.2 mg/100 kcal
DHA	at least about 10 mg/100 kcal	8 mg/100 kcal	8.5 mg/100 kcal

As can be seen in the table, the present invention contains more DHA and more ARA than breast milk. Therefore, the present claims are not anticipated by breast feeding an infant with breast milk.

In addition, as shown in the table above, Applicants' amended claims require levels of DHA and ARA that are higher than the levels of DHA and ARA

[1] The conversions presented in this table are based on the Examiner's calculations of the amounts of DHA and ARA in grams per liter in Kyle's formula, as first presented in paper number 13 dated May 7, 2002. The conversions are also based on a typical infant formula containing 20 kcal per fluid ounce and on the accepted assumption that the daily caloric intake of an infant is 100 - 120 kcal/kg, as stated by the Examiner in paper 21.

found in Kyle's formula. For example, the highest level of DHA disclosed by Kyle is 26.2 mg/100 kcal, and the highest level of ARA disclosed by Kyle is 8.5 mg/100 kcal (calculated from Table 2 in Kyle). These levels of DHA and ARA recited in Kyle, which by its disclosure is intended to mimic human breast milk (col. 2, lines 16-21 and lines 40-41; col. 10, lines 12-16 and 27-30; col. 11, lines 5-7; col. 13, lines 54-55 and 34-36; col. 16, lines 29-3; claims 1, 8, 9, and 20-22), are comparable to the DHA and ARA levels found in breast milk. Applicants' formula, however, requires more of these beneficial fatty acids and, therefore, the teachings of Kyle do not anticipate the presently-amended claims 1 and 14 and the new claims 21 and 22.

II. Rejection of claims 1-8 and 14-20 under 35 U.S.C. §103 as obvious over U.S. Patent No. 5,374,657 to Kyle in view of Crozier, G.L., *et al.*, (Monatschrift Fur Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98)

The Examiner also rejected claims 1-8 and 14-20 under 35 U.S.C. § 103(a) as being obvious over Kyle in view of Crozier (Monatschrift Fur Kinderheilkunde, Vol. 147, No. 7, 1995, pages 95-98). Applicants contend that this rejection has also been mooted in light of the amendments to claims 1 and 14 presented herein.

Even if one of ordinary skill in the art were to combine Kyle and Crozier, a combination that Applicants contend is not suggested by the prior art, the combination would still not teach or suggest every one of the limitations in the amended claims and new claims of the present application. See MPEP § 2142 - § 2143 (explaining that the prior art references, when combined, must teach or suggest all the claim limitations). As explained above, the levels of DHA and ARA required by Applicants' claims are higher than those disclosed by Kyle. Crozier fails to disclose any suitable levels of DHA

and ARA. Moreover, there is no motivation to be found in Kyle or Crozier to raise the levels of DHA and ARA. Therefore, the levels of DHA and ARA now required by the claims are simply missing from a combination of Kyle and Crozier and the claims cannot be obvious in light of that combination.

III. Further clarification of experimental data as requested by Examiner

The Applicants' surprising discovery is that, by feeding preterm infants a formula containing certain amounts of DHA and ARA, an unexpected enhancement in weight gain is achieved for infants fed the presently-claimed formula as compared to preterm infants fed traditional formulas lacking these fatty acids. During the interview, the Examiner requested that the Applicants clarify and explain in more detail the findings of an enhancement in weight gain for infants fed a formula having the claimed amounts of DHA and ARA.

This discovery is illustrated by the data presented in the Applicants' specification. Table 3 (page 28 of the Application) shows the actual mean weight gains for three groups of preterm infants, under the column "least square mean", with weight gains of 30.7 grams/day (g/d) for the Control group, 33.3 g/d for the DHA group, and 34.7 g/d for the DHA+ARA group. Table 5 of the Application shows the p-values ($p<0.05$ is considered significant) for the post-hoc analyses of weight gain (least square means in Table 3). The Table 5 p-values are associated with the means and standard errors in Tables 3 and 4 and clearly demonstrate a significant difference in weight gain between the Control and DHA+ARA groups, with a p-value of 0.004 for weight gain during study formula phase. This is also illustrated in Figure 1 of the Application, which is a graphical representation of the weight gain results (means in Table 3), with the statistical

difference between the DHA+ARA and Control groups from the two-tailed post-hoc analysis indicated by the asterisk (*). Further, at page 23, lines 7-13 of the Application, Applicants report these results as follows:

> Post-hoc analysis reveals that infants on DA [DHA & ARA-enhanced formula] grew faster than infants receiving C [regular formula] and D [DHA-enhanced formula] (See table 5 and figure 1). This enhanced growth provided faster "premature infant catch-up" compared to C and D. Weight achieved by the DA group (3198 g) was higher than C (3075 g) and D (3051 g) at 40 weeks post-conceptual age but had not fully caught up to the term weight (3438 g) of group H [breast-fed term infants] (See table 4 and figure 2). This catch up trend continued through 48 to 57 weeks by which time the mean weight of group DA did not differ from group H while groups C and D remained significantly lower. (*emphasis added*).

In summary, in view of the foregoing arguments and amendments, we respectfully submit that claims 1-5, 14-17, and 21-22 are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application. We invite the Examiner to telephone the undersigned should any issues remain after the consideration of this response.

Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Respectfully requested,

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